



Food and Drug Administration
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April 22, 2015

Reverse Medical Corporation
Ms. Laura Heaton
Associate Director of Regulatory Affairs
13700 Alton Parkway, Suite 167
Irvine, CA 92618

Re: K150108

Trade/Device Name: Reverse Medical Micro Vascular Plug (MVP-7 & MVP-9)
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: March 20, 2015
Received: March 23, 2015

Dear Laura Heaton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150108

Device Name

Reverse Medical Micro Vascular Plug (MVP-7, MVP-9)

Indications for Use (Describe)

The Reverse Medical Micro Vascular Plug (MVP-7, MVP-9) System is intended for use to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared January 15, 2015

Sponsor Reverse Medical Corporation

Address and Registration # The registration number of the manufacturer and sterilization sites for both vascular embolization devices are as follows:

Manufacturer	Sterilization Site
Reverse Medical Corporation 13700 Alton Parkway, Suite 167 Irvine, CA 92618 FDA Registration #: 3007170829	Parter Medical 17115 Kingsview Avenue Carson, CA 90746 FDA Registration #: 2024311

Contact Person Laura Heaton, Associate Director of Regulatory Affairs
E-mail: Laura.Heaton@covidien.com

Device Name The device trade names and common/classification names are:

Device Trade Name	Common/Classification Name
Reverse Medical Micro Vascular Plug	Vascular Embolization Device

Device Class Vascular embolization devices have been classified as Class II, KRD under 21 CFR §870.3300. The Class III Summary and Certification requirement as described in 21 CFR §807.87(j) and §807.94 do not apply to this device and submission. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for vascular embolization devices.

Predicate Device Information The predicate device is the Reverse Medical Micro Vascular Plug (MVP-3Q and MVP-5Q), K141313, concurrence date June 18, 2014. The predicate device is also Micro Vascular Plug (MVP-3) K123803 concurrence date July 2, 2013 and also (MVP-5) K133282 concurrence date Nov. 27, 2013.

Purpose of Submission The purpose of this special 510(k) submission is to obtain market clearance for two (2) modifications of the MVP System. The first is to change the outer diameter and the length of the implant. The second is to the outer diameter of the delivery wire. These changes allow for the obstruction of larger blood vessels in the peripheral vasculature.

Indications for Use and Intended Use The Reverse Medical Corporation MVP Micro Vascular Plug System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Device Description Reverse Medical® MVP® Micro Vascular Plug System consists of a micro vascular occlusion plug that is attached to a composite delivery wire and is intended to be delivered to the treatment site through a catheter. The MVP occlusion plug is a self-expandable, ovoid-shaped frame made from nitinol and incorporates a PTFE cover over the proximal portion of the ovoid. The plug device is secured at both ends with

platinum marker bands. The proximal marker band is attached to a delivery wire that is used to push the plug device through a commercially available catheter to the intended treatment site. After satisfactory deployment of the plug device at the treatment site, the implant is detached from the delivery wire by rotating the wire counter clockwise.

Technical Characteristics The modified devices have the same technological characteristics as the predicate devices.

	K141313	K123803/K133282	Submission Subject		
Feature	MVP-3Q/MVP-5Q Predicate	MVP-3/MVP-5 Predicate	MVP-7 Device	MVP-9 Device	Comparison of Device to RM Predicate
Indications for Use	To obstruct or reduce the rate of blood flow in the peripheral vasculature	To obstruct or reduce the rate of blood flow in the peripheral vasculature	To obstruct or reduce the rate of blood flow in the peripheral vasculature	To obstruct or reduce the rate of blood flow in the peripheral vasculature	Identical Indications for Use
Manufacturer	Reverse Medical (RM) Corp.	Reverse Medical (RM) Corp.	Reverse Medical (RM) Corp.	Reverse Medical (RM) Corp.	Identical manufacturer
Materials of Construction	Nitinol, PTFE, Platinum, Solder, Polypropylene sheath, Urethane, Cyanoacrylate	Nitinol, PTFE, Platinum, stainless steel, Solder, Polypropylene sheath, Urethane, Cyanoacrylate	Nitinol, PTFE, Platinum, stainless steel, Solder, Polypropylene sheath, Urethane, Cyanoacrylate	Nitinol, PTFE, Platinum, stainless steel, Solder, Polypropylene sheath, Urethane, Cyanoacrylate	Identical Materials
Plug (Implant) description	Self-expandable, ovoid shaped frame with a PTFE cover over the proximal portion	Self-expandable, ovoid shaped frame with a PTFE cover over the proximal portion	Self-expandable, ovoid shaped frame with a PTFE cover over the proximal portion	Self-expandable, ovoid shaped frame with a PTFE cover over the proximal portion	Identical Implant material configuration
Plug Diameter, Unconstrained	MVP-3Q: 5.3 mm MVP-5Q: 6.5 mm	MVP-3: 5.3 mm MVP-5: 6.5 mm	9.2 mm	13.0 mm	Larger implant OD
Plug Length, Unconstrained	12 mm	12 mm	16 mm	18 mm	Longer implant

Reverse Medical Corporation
Special 510(k): Device Modification MVP-7 and MVP-9

					Length
Target Vessel Diameter	MVP-3Q: 1.5-3.0 mm MVP-5Q: 3.0-5.0mm	MVP-3: 1.5-3.0 mm MVP-5: 3.0-5.0mm	5.0 – 7.0 mm	7.0 – 9.0 mm	Larger target vessel diameter
Method of Placement	Delivery wire through a microcatheter MVP-3Q: 0.021"-0.027" ID MVP-5Q: 0.027" ID	Delivery wire through a microcatheter MVP-3: 0.021"-0.027" ID MVP-5: 0.027" ID	Delivery wire through a 0.041" ID catheter	Delivery wire through a 0.043" ID catheter	Identical Delivery through a larger catheter
Radiopaque Markers	Platinum marker bands at each end of the plug	Platinum marker bands at each end of the plug	Platinum marker bands at each end of the plug	Platinum marker bands at each end of the plug	Identical marker bands
Proximal End of Plug Configuration	Proximal marker band attached to delivery wire	Proximal marker band attached to delivery wire	Proximal marker band attached to delivery wire	Proximal marker band attached to delivery wire	Identical proximal end plug configuration
Delivery Wire Length	160-180 cm	160-180 cm	160-180 cm	160-180 cm	Identical Delivery Wire Length Range
Detachment System	Mechanical	Electrolytic	Mechanical	Mechanical	Identical
Sterilization Process	EO	EO	EO	EO	Identical
Accessories	Torquer	Detachment Box and Cable Set	Torquer	Torquer	Identical

Performance Tests- Non-Clinical

Due to the changes in the dimensional characteristics the following design verification tests were conducted in accordance with Reverse Medical Design Control procedures. All testing was performed on units that were sterilized and met all inspection criteria. Tests on the Reverse Medical MVP System included:

- Dimensional Inspection
- Visual Inspection
- Catheter compatibility within "Simulated Use Vascular Model"
 - Flexibility within catheter
 - Delivery wire kinking assessment

- Multiple deployments and withdrawals through catheter
 - Force required to deploy and retract device within catheter
- Detachment Evaluations
 - Number of turns required to detach implant
 - Torque strength of detachment junction
- Galvanic Corrosion per ASTM G71
- MRI Compatibility per ASTM F-2503

Basis for Determination of Substantial Equivalence

Upon reviewing the performance data and comparing intended use, design, materials, principle of operation and overall technological characteristics, the modified Reverse Medical MVP System is determined to be substantially equivalent to the currently marketed Reverse Medical MVP System. Differences do not raise any issues of safety or effectiveness.